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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,861	03/24/2000	Josephus Christianus Maria Smeekens	ARNO115313	2637

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EXAMINER
FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/534,861	Smeekens et al
Examiner	**Group Art Unit**
Fox	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 12/27/02.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☑ Other Sequence Error Report

Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The communication filed 27 December 2002 is not fully responsive to the Office communication mailed 09 July 2002 for the reason(s) set forth on the attached CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Since the above-mentioned reply appears to be *bona fide* attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of **ONE (1) MONTH** from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claim 1 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,147,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last Office action.

Applicants' intent to file a Terminal Disclaimer is noted. The rejection will be maintained until receipt of a properly executed Terminal Disclaimer.

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to plant transformation with the native barley fructosyltransferase gene or mutant bacterial fructosyltransferase genes for the production of oligosaccharides, does not reasonably provide enablement for isolated plant fructosyltransferase genes from any other species, for the mutation of any plant fructosyltransferase gene to lower the degree of polymerization of the end product, or for the use of any other gene encoding any other enzyme for the production of oligosaccharides in transformed plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 3-6 of the last Office action.

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 6-7 of the last Office action.

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/12386 (CALGENE), as stated on pages 7-8 of the last Office action.

No claim is allowed.

Applicant's arguments filed 27 December 2002 have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the disclosure of simple assays for fructosyltransferase activity, the disclosure of a method for isolating a

fructosyltransferase gene, the assertion in the specification that native fructosyltransferase genes may be mutated, and the lack of a recitation in the claims of a method of isolating a fructosyltransferase gene from all plant species.

The Examiner maintains that the claims broadly read on methods for isolating any fructosyltransferase gene, which would include isolation from any plant species. Thus, the claim reads on a multitude of inoperative embodiments. See Atlas Powder v. DuPont, 224 USPQ 409, 414 (Fed. Cir. 1984), where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation.

Furthermore, the Examiner maintains that Applicants' mere assertions regarding the ease of isolating other fructosyltransferase genes or mutating them using proposed methods are not sufficient to overcome the actual evidence provided by the Examiner in the form of scientific reasoning and publications.

Applicants urge that the written description rejection is improper, given the teachings of *Enzo Biochem*, the failure of Applicants to claim nucleotide sequences *per se*, and the disclosure of four species by Applicants.

The Examiner maintains that *Enzo* involved a different fact pattern; namely, whether the deposit of a nucleic acid molecule was sufficient to provide an adequate written description of a claim limited to that deposited molecule. Furthermore, the Court in *Enzo* did not provide a final decision stating that a deposit alone is sufficient; they merely remanded the case back to the District Court for further review. In addition, the Court was considering whether the deposit was

adequate to describe a particular species, namely a claim drawn to that deposited nucleic acid molecule, rather than an entire genus. In the instant situation, Applicants have not deposited any sequences, and are not limiting their claims to a particular sequence.

Regarding Applicants' claimed methods, the Examiner maintains that the Written Description Guidelines published in the Federal Register, Vol. 66, No. 4, on Friday January 5, 2001, pages 1099-1111, indicate that if a particular product such as a nucleotide sequence is not adequately described, then methods of using that product are also inadequately described.

Regarding Applicants' disclosure, Applicants have only provided guidance for the following species: a native or mutated *Streptococcus mutans* gene and a native barley gene. While an onion enzyme was purified, no sequencing of the enzyme or gene encoding it was provided, and no other plant species' enzyme or gene was isolated or sequenced. Furthermore, no correlation was demonstrated between particular structural features (such as conserved *gene* sequences) and functional properties (enzyme activity of the encoded protein), as required by the Written Description Guidelines. See MPEP 2163.

Applicants urge that the art rejection is improper, given the failure of the reference to teach a method for producing high molecular weight polysaccharides in plants. The Examiner maintains that the claim is not drawn to the production of high-molecular weight oligosaccharides. The reference teaches plant transformation with genes encompassed by the claimed genus for the production of oligosaccharides, as stated in the last Office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 21, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638